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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,104	03/19/2007	Valerie Arranz	021305-00294	6158
4372 7590 03/10/2011 ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER DEVI SARVAMANGALA 7N	
			ART UNIT 1645	PAPER NUMBER
			NOTIFICATION DATE 03/10/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

# Office Action Summary

**Application No.**

10/568,104

**Applicant(s)**

ARRANZ, VALERIE

**Examiner**

S. Devi, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/29/10.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.  
4a) Of the above claim(s) 1-9, 12 and 13 is/are withdrawn from consideration.  
5) ☒ Claim(s) 14 is/are allowed.  
6) ☒ Claim(s) 10 and 11 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Discrepancy's Patent Drawing Review (PTO-940)  
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **RESPONSE TO APPLICANT'S AMENDMENT**

### **Applicant's Amendment**

- 1) Acknowledgment is made of Applicant's amendment filed 10/19/10 in response to the non-final Office Action mailed 07/22/10.

### **Status of Claims**

- 2) Claims 10 and 11 have been amended via the amendment filed 05/04/10.  
New claim 14 has been added.  
Claims 1-14 are pending.  
Claims 10, 11 and 14 are under examination.

### **English Translated Priority Document**

- 3) Acknowledgment is made of Applicant's submission of the English translated priority document filed 10/19/10.

### **Prior Citation of Title 35 Sections**

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

- 6) The objection to the specification made in paragraph 7(A) of the Office Action mailed 07/22/10 is withdrawn in light of Applicant's amendment to the specification.

### **Rejection(s) Withdrawn**

7) The rejection of claims 10 and 11 made in paragraph 9 of the Office Action mailed 07/22/10 Claims 10 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

8) The rejection of claims 10 and 11 made in paragraph 11 of the Office Action mailed 07/22/10 under 35 U.S.C. § 102(e)(1) as being anticipated by Avrameas et al. (US 2003/0199677 A1 – Applicant's IDS) ('677), is withdrawn in light of Applicant's amendment to the claims.

### **New Rejection(s) Necessitated by Applicant's Amendment**

#### **Double Patenting Rejection(s)**

9) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

**10)** Claims 10 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of the co-pending application 12/278,912, drawn to a chimeric polypeptide composition comprising a first domain having the amino acid sequence of SEQ ID NO: 3 and a second domain that comprises a lysosomal enzyme, i.e., an anti-bacterial compound. Although the conflicting claims are not identical, they are not patentably distinct from each other because the SEQ ID NO: 3 of the co-pending application present with the antibacterial compound has 100% sequence identity with the instantly recited SEQ ID NO: 3 recited in the instant claims. See the sequence alignment below:

US-12-278-912-3  
Sequence 3, Application US/12278912  
Publication No. US20100221235A1  
GENERAL INFORMATION  
APPLICANT: Arranz, Valerie  
TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR TREATING LYSOSOMAL STORAGE DISEASES  
FILE REFERENCE: 62745.000028  
CURRENT APPLICATION NUMBER: US/12/278,912  
CURRENT FILING DATE: 2008-08-08  
PRIOR APPLICATION NUMBER: PCT/IB2007/000301  
PRIOR FILING DATE: 2007-02-08  
PRIOR APPLICATION NUMBER: EP 06290221.8  
PRIOR FILING DATE: 2006-02-08  
NUMBER OF SEQ ID NOS: 48  
SOFTWARE: PatentIn version 3.1  
SEQ ID NO 3  
LENGTH: 17  
TYPE: PRT  
ORGANISM: Homo sapiens  
FEATURE:  
OTHER INFORMATION: DPV6-Cell penetrating peptide  
US-12-278-912-3

Query Match 100.0%; Score 89; DB 8; Length 17; Best Local Similarity 100.0%;

Matches 17; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

Qy	1	GRPRESGKKRKRRLKP	17
Db	1	GRPRESGKKRKRRLKP	17

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Rejection(s) under 35 U.S.C. § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in–

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

12) Claims 10 and 11 are rejected under 35 U.S.C. § 102(e)(1) as being anticipated by Avrameas et al. (US 2003/0199677 A1, of record) ('677).

Avrameas et al. ('677) taught a composition comprising the cell-penetrating peptides having the amino acid sequence of SEQ ID NO: 21, wherein the peptides have the advantageous capacity to allow transport of active substances through biological membranes and barriers. The peptides are coupled to an active substance. The peptide of SEQ ID NO: 21 contains a salicylic motif spacer arm. The peptide is combined covalently or non-covalently to one substance of interest or some substances of interest such as an antibody, lysozyme, antibacterial cationic peptide, or an antibiotic (i.e., antibacterial compound) for internalization in to cells in vivo or in vitro and for treating or preventing a disease. A sequence search performed at the Office indicates that the prior art peptide of SEQ ID NO: 21 has a

sequence that is 100% identical in structure to the instantly recited SEQ ID NO: 3. For example, the peptide coupled to lysozyme inhibited the growth of the Gram negative bacteria, E. coli, and therefore the composition is for the control of the Gram negative E. coli. See the sequence alignment below; and paragraphs [0085], [0068], [0069], [0078], [0079], [0085], [0151], [0242], [0243], [0495], [0498], [0501] to [0504]; Example 28; and claims 59-61.

US-10-231-889-21

Sequence 21, Application US/10231889

Publication No. US20030199677A1

GENERAL INFORMATION:

APPLICANT: Avrameas, Eustrate

APPLICANT: Ternynck, Therese

TITLE OF INVENTION: Amino Acid Sequences Facilitating Penetration Of A Substance Of Interest

TITLE OF INVENTION: Into Cells And/Or Nuclei

FILE REFERENCE: 20440-001

CURRENT APPLICATION NUMBER: US/10/231,889

CURRENT FILING DATE: 2002-08-29

PRIOR APPLICATION NUMBER: PCT/FR00/02621

PRIOR FILING DATE: 2001-03-01

PRIOR APPLICATION NUMBER: FR00/02621

PRIOR FILING DATE: 2000-03-01

NUMBER OF SEQ ID NOS: 51

SOFTWARE: PatentIn Ver. 2.1

SEQ ID NO 21

LENGTH: 17

TYPE: PRT

ORGANISM: Homo sapiens

US-10-231-889-21

Query Match 100.0%; Score 89; DB 4; Length 17; Best Local Similarity 100.0%;

Matches 17; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

Qy	1	GRPRESGKKRKRRLKP	17
Db	1	GRPRESGKKRKRRLKP	17

Furthermore, the preamble limitation 'for the control of Gram negative bacteria' represents the intended use of the claimed composition and has no patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and

wherein the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 10 and 11 are anticipated by Avrameas et al. ('677).

### **Remarks**

**13)** Claims 10 and 11 stand rejected. Claim 14 is allowable.

**14)** Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**15)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**16)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for



published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**17)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's acting supervisor, Gary Nickol, can be reached on (571) 272-0835.

/S. Devi/  
Primary Examiner  
AU 1645

March, 2011